UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

AMBER OLMSTEAD,

Plaintiff,

v. **3:17-CV-387 (FJS/DEP)**

BAYER CORP.; BAYER HEALTHCARE, LLC; BAYER ESSURE, INC., f/k/a Conceptus, Inc.; BAYER HEALTHCARE PRAMACEUTICALS, INC.; and BAYER, A.G.,

Defendants.

APPEARANCES	**OF COUNSEL**
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SCULLIN, Senior Judge

MEMORANDUM-DECISION AND ORDER

I. INTRODUCTION

Pending before the Court is Defendants' motion to dismiss Plaintiff's complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. *See* Dkt. No. 6.

II. BACKGROUND

A. Statutory and regulatory background

The Food and Drug Administration ("FDA") regulates medical devices pursuant to the Food, Drug, and Cosmetics Act ("FDCA") and the Medical Device Amendments of 1976 ("MDA"). *See* 21 U.S.C. § 360c *et seq*. The MDA, in turn, categorizes certain devices as Class III medical devices when the less stringent classifications cannot provide reasonable assurance of their safety and effectiveness, and the devices are used either "in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or they "present[] a potential or unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C).

A Class III medical device is required to undergo FDA's premarket approval process ("PMA") before being marketed to the public. PMA is a "rigorous" process. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). To be awarded PMA, a device manufacturer must submit a substantial application including

> full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling.

Riegel v. Medtronic, Inc., 552 U.S. 312, 318 (2008) (quoting 21 U.S.C. § 360e(c)(1)).

The FDA will grant PMA only if it finds that there is a "reasonable assurance" of the device's "safety and effectiveness." 21 U.S.C. § 360e(d). "The agency must 'weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Riegel*, 552 U.S. at 318 (quoting [21 U.S.C.] § 360c(a)(2)(C)). Therefore, the FDA may "approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Id*. Moreover, the PMA includes review of the device's proposed labeling. In that regard, "[t]he FDA evaluates safety and effectiveness under the conditions of use set forth on the label," *id*. (citing [21 U.S.C.] § 360c(a)(2)(B)), "and must determine that the proposed labeling is neither false nor misleading," *id*. (citing [21 U.S.C.] § 360e(d)(1)(A)).

After PMA is issued, "the MDA forbids a manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id*. at 319 (citing [21 U.S.C.] § 360e(d)(6)(A)(i) [now at § 360e(d)(5)(A)(i)]). Furthermore, the manufacturer must inform the FDA if it learns new information about the device and must report when the device has caused or contributed to death or serious injury. *See id.* (citing [21 C.F.R.] § 803.50(a)). If at any time the FDA determines a device is unsafe or ineffective under the terms of its labeling, it may withdraw premarket approval. *See id*. at 319-20 (citing [21 U.S.C.] § 360e(e)(1)) (other citation omitted).

Essure is a method of permanent female contraception. In 2002, FDA granted Essure PMA as a Class III device, and FDA has never withdrawn or suspended that PMA.

B. Plaintiff's complaint

In 2012, Plaintiff spoke with her gynecologist because she wanted to learn more about permanent birth control. *See* Dkt. No. 2, "Plaintiff's Complaint," at ¶ 9. According to Plaintiff, Dr. Carol Miller advised her that Essure was "safe, effective, and permanent." *See id*. On January 31, 2013, Plaintiff went to Wilson Hospital to have the device implanted. *See id.*

According to Plaintiff, after Essure was implanted, "[s]he had her period for six months straight and was not able to use tampons." *See id.* at ¶ 10. Furthermore, Plaintiff asserts that, "[w]ithin three months, [she] began to suffer from severe headaches, something she had rarely had before." *See id.* at ¶ 11. Plaintiff also alleges that she experienced "extreme fatigue" and "developed lower back pain[.]" *See id.* Moreover, Plaintiff asserts that she was no longer able to enjoy sexual relations with her husband because the pain was so severe. *See id.* at ¶ 12.

Plaintiff alleges that, in the summer of 2015, she ran into a friend, who told her she had an "Essure belly."[1] *See id*. at ¶ 13. During this conversation, Plaintiff asserts that her friend told her that the FDA had not approved Essure and that other women were having similar problems with Essure. *See id.* at ¶ 14.

Thereafter, Plaintiff's pain increased; and, on September 9, 2016, she went to Wilson Hospital "literally doubled over in a fetal position because of the severe abdominal pain." *See id*. at ¶ 15. A doctor performed an ultra sound but everything appeared normal. *See id*. at ¶ 16. Plaintiff was told to follow-up with her own doctor. *See id.* In October 2016, Plaintiff visited Dr. Miller and Dr. Kondrup, who ordered a 3-d ultrasound, which revealed that one of the coils of the Essure was "sticking out of the uterus by about one inch." *See id.* at ¶ 17.

[1] An "Essure Belly" is apparently a metaphor for being bloated.

Based on the foregoing, Plaintiff sued Defendants in New York Supreme Court, Broome County, alleging first that Defendants knew or should have known that Essure was dangerous, yet they represented that it was a safe and effective method of permanent birth control, *see id*. at ¶¶ 19-28 (negligent misrepresentation); second, that Essure was unreasonably dangerous and defective, *see id*. at ¶¶ 29-33 (strict liability); third, that Plaintiff was never warned about the risks of Essure prior to having the device implanted and was never warned that her adverse side-effects could be related to Essure, *see id.* at ¶¶ 34-40 (failure to warn); fourth, that Defendants warranted that Essure was safe when it was not, *see id.* at ¶¶ 41-44 (breach of express warranty); and, finally, that Defendants impliedly warranted that the product was safe, *see id.* at ¶¶ 45-49 (breach of implied warranty).

Defendants removed this case to federal court asserting this Court's diversity jurisdiction, *see* Dkt. No. 1, and thereafter filed the pending motion to dismiss Plaintiff's claims, *see* Dkt. No. 6. Defendants' principal argument is that the MDA expressly or impliedly preempts Plaintiff's claims.

III. DISCUSSION

A. Standard of review

Courts use a two-step inquiry when addressing a Rule 12(b)(6) motion. "First, they isolate the moving party's legal conclusions from its factual allegations." *Hyman v. Cornell Univ.*, 834 F. Supp. 2d 77, 81 (N.D.N.Y. 2011). Second, courts must accept factual allegations as true and "determine whether they plausibly give rise to an entitlement to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). A pleading must contain more than a "blanket assertion[ ] of entitlement to relief." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 n.3 (2007). Thus, to withstand a motion to dismiss, a pleading must be "plausible on its face" such that it contains

"factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citation omitted).

B. Preemption

The MDA contains the following express preemption clause:

> (a) General rule
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).[2]

This express preemption clause makes clear that state laws that impose obligations "different from or in addition to" the requirements of the MDA are expressly preempted. 21 U.S.C. § 360k(a)(1); *see also Riegel*, 552 U.S. at 321 (quotation omitted). Thus, common law claims challenging the safety of an FDA-approved medical device may survive preemption only if they are "premised on a violation of FDA regulations" where state law provides a damages remedy for such violations. *Riegel*, 552 U.S. at 330. In such a case, the common law claims run

[2] Plaintiff's argument that there is a strong presumption against preemption and that this presumption applies to the MDA's express preemption clause is frivolous. *See Puerto Rico v. Franklin California Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016) (holding that, when the "statute 'contains an express pre-emption clause,' we do not invoke any presumption against pre-emption but instead 'focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent'" (quotation and other citation omitted)).

"'parallel,' rather than add to, federal requirements." *Id*. (quoting *Lohr*, 518 U.S., at 495, 116 S. Ct. 2240) (other citation omitted).

The MDA also provides that all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court, in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), construed § 337(a) as barring suits by private litigants "for noncompliance with the medical device provisions." *Id*. at 349 n.4. In other words, a plaintiff's cause of action is impliedly preempted when it is premised solely on a violation of the FDCA.

In sum,

> "*Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)."

In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010) (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). Accordingly, avoiding express and implied preemption is a difficult task that has been compared to "navigating between Scylla and Charybdis." *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1340 (10th Cir. 2015) (citation omitted).

The first step of this onerous task is for the plaintiff to identify a parallel federal law upon which she has based her state-law claims. Defendants contend that Plaintiff's complaint utterly fails this first step. In that regard, Defendants assert that, "[i]n the entirety of her Complaint, Plaintiff does not allege that [Defendants] violated a single federal law, regulation, or other requirement." *See* Dkt. No. 6-1 at 13.

In response, Plaintiff describes the Current Good Manufacturing Practices ("CGMPs"), *see* 21 C.F.R. § 820.1 *et. seq*.; however, Plaintiff fails to explain how Defendants violated the CGMPs.[3] More importantly, the CGMPs "'are intended to serve only as "an umbrella quality system" providing "general objectives" medical device manufacturers must seek to achieve.'" *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 278-79 (E.D.N.Y. 2009) (quotation omitted); *accord In re Medtronic*, 592 F. Supp. 2d at 1157 (referring to CGMPs as "simply too generic, standing alone, to serve as the basis for Plaintiff's manufacturing-defect claims"). "Since these regulations are open to a particular manufacturer's interpretation, allowing them to serve as a basis for a claim would lead to differing safety requirements that might emanate from various lawsuits." *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009). Thus, allowing a suit to continue on the basis of the CGMPs would necessarily impose "standards that are 'different from, or in addition to' those imposed by the MDA -- precisely the result that the MDA preemption provision seeks to prevent." *Id*. (citations omitted)

Thus, Plaintiff has failed to identify a single parallel federal statute or regulation related to any of her claims. Therefore, the Court concludes that, as a matter of law, the MDA expressly preempts Plaintiff's claims.[4]

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[3] Plaintiff also cited several federal regulations and statutes ostensibly relevant to her claims. *See* Dkt. No. 14 at 5 n.3. However, Plaintiff failed to make any attempt to connect this string of citations to the factual allegations in her complaint.

[4] Plaintiff also argues that Essure's PMA is "invalid" supposedly because Defendants have failed to comply with various conditions in their PMA. *See* Dkt. No. 14 at 8-9. Plaintiff's position assumes that failure to comply with PMA conditions automatically invalidates the PMA; however, the Code of Federal Regulations vests authority and discretion in the FDA to withdraw premarket approval from a device if there is a violation of conditions. In that regard, "the regulations specifically empower the FDA to 'issue an order withdrawing approval of a PMA if, from any information available to the agency, FDA determines that . . . (2) Any postapproval requirement imposed by the PMA approval order . . . has not been met.'" *McLaughlin v. Bayer*

C. Leave to amend -- statute of limitations

Normally, under these circumstances, the Court would permit Plaintiff to amend her complaint as a matter of course to attempt to allege a plausible claim that is not preempted. However, in this case, Defendants additionally argue that Plaintiff's entire complaint is time barred, thus making any proposed amendment futile.

Under New York law, a plaintiff must commence a personal injury action or products liability action within three years of the date of accrual. *See* N.Y. C.P.L.R. § 214(5). This statute of limitations begins to run "from the date of discovery of the injury by the plaintiff or from the date when through the exercise of reasonable diligence such injury should have been discovered by the plaintiff, whichever is earlier." N.Y. C.P.L.R. § 214-c(2). Furthermore, "[t]he three year limitations period runs from the date when plaintiff first noticed symptoms, rather than when a physician first diagnosed those symptoms[.]" *Galletta v. Stryker Corp.*, 283 F. Supp. 2d 914, 917 (S.D.N.Y. 2003) (citations omitted). Therefore, "the significant date is when [P]laintiff began experiencing symptoms, not when [a doctor] diagnosed them." *Id*. (citing *Wetherill v. Eli Lilly & Company*, 89 N.Y.2d 506, 515, 655 N.Y.S.2d 862, 678 N.E.2d 474 (1997)) (other citation omitted).

Plaintiff commenced this action on January 31, 2017. Accordingly, any claim based on an injury Plaintiff discovered, or should have discovered, prior to January 31, 2014, is time-barred.

Corp., 172 F. Supp. 3d 804, 815 n.6 (E.D. Pa. 2016) (quoting 21 C.F.R. § 814.46(a)). Plaintiff does not allege that the FDA has withdrawn Essure's PMA; thus, the PMA remains effective.

Plaintiff's complaint alleges that she first began to feel symptoms related to the Essure device as early as immediately after the device was implanted but no later than three months afterwards, *i.e.*, approximately April 30, 2013. *See* Dkt. No. 2 at ¶ 10 (alleging she had had her period for six months straight and had to take the birth control pill); ¶ 11 (alleging that, "[w]ithin three months, [she] began to suffer from severe headaches, . . . extreme fatigue[, and] . . . lower back pain"); ¶ 12 (alleging that she was unable to enjoy sexual relations). Clearly Plaintiff began experiencing symptoms more than three years before she filed this case. It is of no consequence, therefore, that Plaintiff did not learn that the cause of her injury might have been the result of the Essure device until the summer of 2015

Nor can the so-called "two-injury" rule save her case. "Pursuant to the rule, 'the Statute of Limitations starts to run anew upon the discovery of a second injury' caused by the same wrong[.]" *Suffolk Cty. Water Auth. v. Dow Chem. Co.*, 121 A.D.3d 50, 60 (2d Dep't 2014) (quotation and other citation omitted). "However, the two-injury rule does not apply to an injury which is the 'outgrowth, maturation or complication of the original contamination[.]'" *Id.* (quoting *DiStefano v. Nabisco*, 282 A.D.2d at 705) (other citations omitted). "Rather, the second injury must be 'separate and distinct' and arise independently of prior injuries . . ., and must be '"qualitatively different from that sustained earlier. . . ."'" *Id.* (internal quotation and other citations omitted).

In this case, Plaintiff's complaints of pain in 2016 are qualitatively similar to the injuries she allegedly suffered as early as 2013. Furthermore, the alleged coil protrusion is merely an "outgrowth, maturation, or complication of the original contamination." *Id.* Therefore, the Court finds that Plaintiff's claims are time-barred and, therefore, allowing Plaintiff to amend her complaint under these circumstances would be futile.

IV. CONCLUSION

Having reviewed the entire file in this matter, the parties' submissions, and the applicable law, and for the above-stated reasons, the Court hereby

ORDERS that Defendants' motion to dismiss Plaintiff's complaint, *see* Dkt. No. 6, is **GRANTED**; and the Court further

ORDERS that that the Clerk of the Court shall enter judgment in favor of Defendants and close this case.

IT IS SO ORDERED.

Dated: August 15, 2017
Syracuse, New York

Frederick J. Scullin, Jr.
Senior United States District Judge